AUG 31 2000

K000700

510(K) SUMMARY
(as required by 807.92(c))

Submitter of 510(k):

AJW Technology Consultants, Inc.
962 Allegro Lane
Apollo Beach, FL 33572

Phone: 813-645-2855
Fax: 813-645-2856

Contact Person: Art Ward

Date of Summary: January 10, 2000

Trade Name:

Sensidyne, Inc.
16333 Bay Vista Drive
Clearwater, FL 33760

Classification Name: Oxygen Monitor/Analyzer

Predicate Device:

Miniox 3000	Oxygen Monitor	K961644
Minox IA	Oxygen Analyzer	K935370

Device Description:

The Sensidyne Oxygen Monitor and Analyzer are compact oxygen measurement devices, which may be hand held, table or wall mounted. They measure oxygen levels in a variety of medical applications. Both have touch pad controls and the monitor offers a range of alarm parameters. Each unit is serialized.

Comparison:

Oxygen Monitor Comparative Chart:

Features	Sensidyne Monitor	MSA 3000 Monitor
Indications For Use	Continuous O_2 Monitoring	Same
Alarms	High/ Low O_2	Same
Range	0-100%	0-100%
Display Resolution	0.1%	0.1%
Power Source	2- AA Batteries	1-9-Volt Battery
Sensor Type	Galvanic	Galvanic
Alarm System	Visual/ Audio	Same
Size	5.5"x 3.6"x 1.5"	5.98"x 3.26"x 1.31"
Weight	215 g	198.5 g
Cable Length	10 Ft.	10 Ft.

Oxygen Analyzer Comparative Chart

Features	Sensidyne Analyzer	MSA IA Analyzer
Indications For Use	O_2 % Checking	Same
Sensor	Galvanic	Galvanic
Range	0-100%	0-100%
Display Resolution	0.1%	0.1%
Low Battery Indicator	Visual	Same
Size	5.5"x 3.6"x 1.5"	4 5/8" x 2.5"x 1. 5"
Weight	215 g	260 g
Power Source	2-AA Batteries	1-9 Volt Battery
Cable Length	10 Ft.	10 Ft.

Intended Use: The Sensidyne, Inc. Oxygen Monitor/ Analyzer provides continuous/ temporary measurement of oxygen mixtures in a wide variety of medical applications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 2000

Mr. Howard B. Mills
Sensidyne, Inc.
16333 Bay Vista Drive
Clearwater, FL 33760

Re: K000700
Sensidyne Oxygen Monitor/Analyzer
Regulatory Class: II (two)
Product Code: 73 CCL
Dated: June 26, 2000
Received: June 27, 2000

Dear Mr. Mills:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K000700

Device Name: Sensidyne, Inc. Oxygen Monitor/ Analyzer

Indications For Use:

The Sensidyne, Inc. Oxygen Monitor/ Analyzer provides continuous/temporary measurement of oxygen mixtures in a wide variety of medical applications. The internally mounted gas sensor requires connection to a regulated gas source.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K000700

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)